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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,226	12/20/2001	Ranjani V. Parthasarathy	57313US002	9039

32692 7590 12/14/2004

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EXAMINER	
HANDY, DWAYNE K	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,226	PARTHASARATHY ET AL.	
	Examiner	Art Unit	
	Dwayne K Handy	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *the RCE filed 10/26/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-28,30-55,62-67,77 and 78* is/are pending in the application.

4a) Of the above claim(s) *1,3-28 and 30-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-55, 62-67 and 77-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant has requested that independent claims 1, 20, 26, 28 and 47 be examined and rejoined with the remaining claims upon an indication of allowable subject matter in examined claims 50 and 78. Since the Examiner has not indicated allowable subject matter in claim 50 and 78, the claims remain restricted and unexamined.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 50-53 are provisionally rejected in a previous Office Action under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-58 of copending Application No. 10/417,609 in view of Dusterhoft et al. (6,451,260). This is a provisional obviousness-type double patenting rejection

because the conflicting claims have not in fact been patented. This rejection remains in effect.

4. Claims 50-53 were also provisionally rejected in a previous Office Action under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39-42 of copending Application No. 10/027,222 in view of Dusterhoft et al. (6,451,260). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. This rejection also remains in effect.

The Examiner again notes applicant's desire to address these rejections upon an indication of otherwise allowable subject matter (page 15 of submission dated 10/26/2004). The Examiner also thanks applicant for pointing out a typographical error in the previous action. In the previous action the Examiner stated that claims 50-53 were rejected in view of Application number 10/**272,222** instead of Application number 10/027,222. The Examiner apologizes for the error.

Inventorship

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 50-52, 64, 65, 77 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (6,344,326) in view of Dusterhoft et al. (6,451,260). Nelson et al. teach a microfluidic device for nucleic acid separation and processing. The device is comprised of a number of channels containing fluid control elements and separation media disposed on a substrate. The basic embodiment of the device is described in columns 4 and 5 and includes inlet and outlet passages as well as

channels for distributing solutions through the various channels of the device. Nelson teaches the use of separation media in conjunction with the channels in column 8:

(15) Suitable capture media for proteins include the following. Suitable capture media for proteins include: ion exchange resins, including anion (e.g., DEAE) and cation exchange; hydrophobic interaction compounds (e.g., C4, C8 and C18 compounds); sulfhydryls; heparins; inherently active surfaces (e.g., plastics, nitrocellulose blotting papers); activated plastic surfaces; aromatic dyes such as Cibacron blue, Remazol orange, and Procion red. For carbohydrate moieties of proteins, lectins, immobilized hydrophobic octyl and phenylalkane derivatives can be suitable. For enzymes, analogs of a specific enzyme substrate-product transition-state intermediate can be suitable; for kinases, calmodulin can be suitable. Suitable capture media for receptors include receptor ligand affinity compounds.

(16) As mentioned above, the enrichment channel will comprise at least one inlet and at least one outlet. Of course, where there is a single inlet, the inlet must serve to admit sample to the enrichment channel at an enrichment phase of the process, and to admit an elution medium during an elution phase of the process. And where there is a single outlet, the outlet must serve to discharge the portion of the sample that has been depleted of the fraction retained by the enrichment media, and to pass to the main electrophoretic microchannel the enriched fraction during the elution phase. Depending on the particular enrichment means housed in the enrichment channel, as well as the particular device configuration, the enrichment channel may have more than one fluid inlet, serving as, e.g., sample inlet and elution buffer inlet; or the enrichment channel may have more than one outlet, serving as, e.g., waste outlet and enriched fraction fluid outlet. Where the enrichment channel is in direct fluid communication with the main electrophoretic channel, i.e., the enrichment channel and main electrophoretic flowpath are joined so that fluid flows from the enrichment channel immediately into the main electrophoretic flowpath, the enrichment channel will comprise, in addition to the waste outlet, an enriched fraction fluid outlet through which the enriched fraction of the sample flows into the main electrophoretic flowpath. When convenient, e.g., for the introduction of wash and/or elution solvent into the enrichment channel, one or more additional fluid inlets may be provided to conduct such solvents into the enrichment channel from fluid reservoirs. To control bulk fluid flow through the enrichment channel, e.g., to prevent waste sample from flowing into the main electrophoretic flowpath, fluid control means, e.g., valves, membranes, etc., may be associated with each of the inlets and outlets. Where desirable for moving fluid and entities through the enrichment channel, e.g., sample, elution buffer, reagents, reactants, wash or rinse solutions, etc., electrodes may be provided capable of applying an electric field to the material and fluid present in the enrichment channel.

(17) The next component of the subject devices is the main electrophoretic flowpath. The main electrophoretic flowpath may have a variety of configurations, including tube-like, trench-like or other convenient configuration, where the cross-sectional shape of the flowpath may be circular, ellipsoid, square, rectangular, triangular and the like so that it forms a microchannel on the surface of the planar substrate in which it is present. The microchannel will have cross-sectional area which provides for capillary fluid flow through the microchannel, where at least one of the cross-sectional dimensions, e.g., width, height, diameter, will be at least about 1 mm, usually at least about 10 mm, but will not exceed about 200 mm, and will usually not exceed about 100

mm. Depending on the particular nature of the integrated device, the main electrophoretic flowpath may be straight, curved or another convenient configuration on the surface of the planar substrate.

Nelson, then, teaches a device with a plurality of process arrays with a plurality of process chambers with solid phase separation media connected by a channel with a valve. Nelson also shows embodiments in which the arrays are arranged radially on the device. Nelson does not teach a solid phase extraction material comprised of a hydrophilic solid support partially embedded within a hydrophobic matrix. Dusterhoft et al. teach a method of making microporous elements for use as filters and membranes in microfiltration, chromatography, adsorption and immobilization of organic and inorganic compounds. The reference also teaches methods of using the microporous elements as well. The microporous elements of Dusterhoft are best shown in Figures 1-5 and described in columns 23. In column 23, Dusterhoft teaches the basic microporous filter element comprised of a spongy-form polymer (2) having embedded microparticles (3) in the aperture of a support member. In the case of Figure 3, the support member is in the form of a tube. As noted in the previous action, Dusterhoft teaches a method of forming the microporous element in column 11:

(75) Typical combinations of resin/solvent/nonsolvent are, for example, one of poly(vinylalcohol-co-ethylene), nitrocellulose, cellulose propionate, or polyvinylacetate as resin, dimethyl sulfoxide as solvent and water as nonsolvent; or polyamides (like Nylon 6,6) as resin, 2,2,2-trichloro ethanol as solvent and acetone as nonsolvent.

(76) Without intending to be bound to theory it is believed that in generating the microporous element according to the present invention the following mechanisms are involved: When the nonsolvent diffuses into the layer of resin solution, the solubility of the resin is gradually decreased. As the limit of solubility is reached the resin begins to precipitate from the solution at individual points. The precipitation of the resin proceeds at the points of initial precipitation. Ultimately, the solvent/nonsolvent is enclosed in large interconnecting enclaves in a solid matrix of resin. The interconnecting enclaves form the liquid-permeable channels of the final

microporous element. If a synthetic resin is used which comprises both hydrophilic and hydrophobic segments, the hydrophobic segments will be forced towards each other and brought into contact with each other as the concentration of nonsolvent in the resin solution increases. There will be interactions between the hydrophobic segments of neighboring molecule chains, which result in the formation of a crystalline hydrophobic backbone of the precipitated resin. The hydrophilic segments will be oriented towards the enclaves filled with solvent/nonsolvent. Accordingly, a microporous element is obtained where the liquid-permeable channels are predominantly hydrophilic. This provides the benefit of biocompatibility. The term "biocompatibility" means that the three-dimensional structure of biopolymers, for example proteins, peptides, nucleic acids, oligonucleotides, polysaccharides or derivatives thereof, is maintained. The interphase forces are less destructive when the polymer surface is rich in hydroxyl, amide or ether groups.

(77) In order to modify the adsorptive properties of the microporous element, the solution of the synthetic resin may further comprise solid microparticles. The micro particles may be composed of silicon dioxide, silica gel, aluminum oxide, titan dioxide, zirconium oxide, glass, carbon or graphite. Also, the particles can be composed of inorganic material, such as calcium phosphate, zinc polyphosphate or the like. Another type of granular microparticles consists of an inorganic core such as microporous silica gel with a microlayer of organic polymer. The pores and the surface of the grain may be modified in a way, that macromolecules are restricted from penetrating into the pores ("Restricted access material"). Also, the micro particles may consist of organic material such as a powder of cured resin, or highly crosslinked polysaccharides, as are available under the sephadex tradename, however care has to be taken in selecting an organic material in that it must not be soluble in the solvent used. The particles can be non-porous or porous, but preferably are porous with a preferred pore size in the range of 1 nm to 500 nm. Generally, the particles have a size from 5 nm to 80 mm, in particular from 0.5 mm to 30 mm, however porous microparticles preferably have a size of 1 mm or more, whereas nonporous microparticles preferably have a size of 1 mm or less. The microparticles can be pretreated, e.g., derivatized, such that the adsorbent properties thereof meet specific requirements. Any kind of commercially available adsorbent particles as used for solid phase extraction or chromatography, such as affinity chromatography with proteins, antibodies, peptides, carbohydrates, nucleic acids, or for ion exchange chromatography, immuno chromatography, hydrophobic interaction chromatography, chelating chromatography and reversed phase chromatography are useful. Materials suited for high performance liquid chromatography are especially useful. For example proteins, such as specific antibodies, lectins, avidin, receptor-proteins, enzymes, synthetic peptides, nucleic acids or oligonucleotides may be attached to the microparticles, either covalently or via linkers. The adsorbent particles have a granular shape, for example spherical. The microparticles may be used, e.g., in an amount of up to 50 mg, preferably 100 ng to 20 mg, per filter element.

(78) In the final microparticle-containing filter element, the outer or inner surfaces of the enclosed microparticles are accessible to an applied liquid sample, and adsorption/immobilization of analytes contained in the liquid sample can take place.

Dusterhoft, then, teaches a resin that contains hydrophobic groups toward the inside of the resin and hydrophilic groups on the surfaces of the liquid permeable

channels of the microporous resin. The Examiner believes the disclosure of a resin with inner hydrophobic properties and outer hydrophilic properties is clearly stated in paragraph 76. Dusterhoft also teaches that these hydrophilic groups on the surface of the microporous channels are key for "biocompatibility" – or use with biomolecules. In paragraph 77, Dusterhoft adds embedded particles and states that the micro particles may be derivatized with oligonucleotides in order for use in ion exchange chromatography. The Examiner believes this would provide a solid phase extraction material that is comprised of hydrophilic particles partially disposed in a hydrophobic matrix. It would have been obvious to one of ordinary skill in the art to combine the microporous elements of Dusterhoft with the device of Nelson. Nelson teaches general ion exchange media, but does not teach solid phase extraction material that is comprised of hydrophilic particles partially disposed in a hydrophobic matrix. One would add the microporous element of Dusterhoft to Nelson to take advantage of the greater surface area provided by the microporous media as well as the increased affinity provided by the increased biocompatibility taught by Dusterhoft.

8. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson and Dusterhoft as applied above, and further in view of Mian et al. (6,319,469). Nelson and Dusterhoft teach every element of claim 53 except for the array arranged radially on the device. Mian teaches a microfluidic device with a plurality of arrays arranged radially on the platform. The arrays are arranged radially in order to take advantage of centripetal force to motivate fluid movement through the channels of the array (Abstract,

Figure 1C, column 3 lines 36-57 and columns 9-11). It would have been obvious to one of ordinary skill in the art to combine the radial arrays of Mian with the teachings of Gjerde. The use of Mian's arrays would allow for the use of centripetal force to drive fluids through the separation media.

9. Claims 54, 55, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson and Dusterhoft as applied above, and further in view of Chisolm et al. (4,399,009). Nelson and Dusterhoft, as described above, teach every element of claims 54, 55, 66 and 67 except for the adhesive matrix and a pattern of particles coated on the matrix. Chisholm teaches an electrolytic cell which contains a semipermeable membrane for coating the electrodes of the cell and separating. The membrane is in sheet form and normally comprises a layer, coating or sheet of a fluorocarbon having cation exchange groups and a second layer which is non-fluorinated or less fluorinated. The layers are held together and in place on the electrode through the use of an adhesive applied to both the hydrophobic and hydrophilic portions (Abstract, column 4 - lines 6-22). It would have been obvious to one of ordinary skill in the art to combine the adhesive from Chisholm with the combined teachings of Nelson and Dusterhoft. The addition of adhesive to the separation media from Nelson and Dusterhoft would allow one to bind the media to the channel containing the media and keep the media in place during use of the device.

10. Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson and Dusterhoft as applied above, and further in view of Kellogg et al. (6,632,399). Nelson and Dusterhoft teach every element of claim 53 except for the particle size specified in these claims. Kellogg teaches a microfluidic device for use in biological fluid assays. In column 40, line 10-47, Kellogg teaches the use of an affinity matrix having 60 micron beads for use in blood component separation. It would have been obvious to one of ordinary skill in the art to combine the particle size of 60 um from Kellogg with the combined teachings of Nelson and Dusterhoft. Kellogg teaches the use of this size in reference to separating blood components. The use of 60 micron particles, then, would be advantageous in a system which analyzes biological samples.

Response to Arguments

11. Applicant's arguments filed 10/26/2004 have been fully considered but they are not persuasive. Applicant has argued that the reference Dusterhoft does not teach a solid phase extraction material that is comprised of hydrophilic particles partially disposed in a hydrophobic matrix. The Examiner respectfully disagrees. As stated above, the Examiner believes the disclosure of a resin with inner hydrophobic properties and outer hydrophilic properties is clearly stated in paragraph 76. Dusterhoft also teaches that these hydrophilic groups on the surface of the microporous channels are key for "biocompatibility" – or use with biomolecules. In paragraph 77, Dusterhoft adds embedded particles and states that the micro particles may be derivatized with oligonucleotides in order for use in ion exchange chromatography. The Examiner

believes this would provide a solid phase extraction material that is comprised of hydrophilic particles partially disposed in a hydrophobic matrix.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Frechet et al. (5,633,290) and Johansson (5,801,237) teach separation media.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
December 10, 2004

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